## UNITED STATES DISTRICT COURT EASTERN DISTRICT OF TEXAS MARSHALL DIVISION

ALLERGAN, INC.,

Plaintiff,

Civil Action No. 2:15-cv-1455-WCB

v.

TEVA PHARMACEUTICALS USA, INC., AKORN, INC., MYLAN PHARMACEUTICALS INC., and MYLAN INC.,

(Consolidated) LEAD CASE

JURY TRIAL DEMANDED

Defendants.

DEFENDANTS' OPPOSITION TO ALLERGAN'S MOTION TO STRIKE CERTAIN PRIOR ART IN THE EXPERT REPORT OF ANDREW CALMAN, M.D.

There are no "undisclosed" or "unselected" prior-art references in Dr. Calman's report.

Doc. No. 340 at 1 ("Motion"). Yet, Allergan—without legal basis—seeks to strike evidence that rebuts its alleged secondary considerations and provides relevant background about the technology and state of the art. This District has repeatedly interpreted Local Patent Rule 3-3 to allow experts to rely on such references. Likewise, the Federal Circuit has repeatedly agreed, holding that references cited as "evidence of the background understanding of skilled artisans" need not be the same "pieces of prior art defining" grounds of invalidity because such "[a]rt can legitimately serve to document the knowledge that skilled artisans would bring to bear in reading the prior art identified . . . ." *Ariosa Diagnostics v. Verinata Health, Inc.*, 805 F.3d 1359, 1365 (Fed. Cir. 2015) (citing *Randall Mfg. v. Rea*, 733 F.3d 1355, 1362–63 (Fed. Cir. 2013)). In its motion to strike, Allergan effectively argues that experts in patent cases cannot cite any references other than the prior art forming the basis of a prior-art-based invalidity contention. Allergan is wrong.

Specifically, Allergan complains that Dr. Calman's report cites ten references (collectively, "Disputed References") not "selected" as prior art by Defendants under L.P.R. 3-3. Motion at 1. But Allergan conspicuously ignores that these background references either rebut Allergan's allegations of long-felt need and unexpected results, or directly show the knowledge of a person of ordinary skill in the art during the relevant timeframe. Tellingly, Allergan never alleges that the Disputed References serve as the basis for some new, previously undisclosed invalidity theory. Indeed, Defendants were surprised by Allergan's filing of the instant motion

because it is a recognized and acceptable practice for experts to use publications as background material for the technology at issue.<sup>1</sup>

#### I. BACKGROUND

#### A. Allergan's Assertions of Secondary Considerations

Over a year ago, on March 11, 2016, Defendants served Allergan with their first set of interrogatories seeking Allergan's positions regarding secondary considerations of nonobviousness. *See* Ex. 1 at 7. Allergan responded on April 14, 2016, alleging unexpected results, long-felt and unmet need, commercial success, and copying. Ex. 2 at 7-10. In particular, Allergan argued that increasing the amount of castor oil produced unexpected results:

- ) "Prior to the invention, there was no reason for a person of skill in the art to double the amount of castor oil disclosed in the prior art formulations. Additionally, a person of skill in the art may have been concerned that increasing the amount of castor oil in the formulation would reduce the bioavailability of cyclosporine." *Id.* at 8.
- Taken together, the results from the pharmacokinetic testing done during the development of Restasis<sup>®</sup> confirm what a person of skill in the art would have expected at that time that increasing the concentration of castor oil in the formulation would lead to decreased bioavailability." *Id*.
- ) "The results of the Phase 2 studies on Restasis® were consistent with that expectation [that increasing the amount of castor oil in the formulation decreased the bioavailability of the drug]." *Id*.
- "Despite all of those previous results, the inventors unexpectedly found that increasing the amount of castor oil in a formulation containing 0.05% cyclosporin from 0.625% to 1.25% actually resulted in a 0.05% cyclosporin formulation with equivalent or better efficacy than the 0.1% formulation. For example, the Phase 3 results showed that it was the 0.05% cyclosporin/1.25% castor oil formulation that

2

<sup>&</sup>lt;sup>1</sup> Defendants' surprise is compounded because Allergan did not raise the present issue until 3:32 pm CT on May 30, 2017—the deadline for filing any motions to strike—when Allergan first requested a meet and confer. Ex. 3. Defendants, who were preparing to file motions for summary judgment, were unavailable to meet and confer at the late hour. However, Defendants made a concerted effort to be available the next day to meet and confer regarding the issues now before the Court. Doc. No. 345. The discussions ended at an impasse and Defendants opposed the motion.

exhibited better scores for Schirmer tear test than did the formulation containing 0.1% cyclosporin and 1.25% castor oil." *Id.* at 9.

"Thus, despite previous expectations and evidence to the contrary, increasing the amount of castor oil in the formulation increased the therapeutic efficacy." *Id.*Allergan further argued that there was "a long-felt and unmet need for a treatment of dry eye disease." *Id.* "Conventional medication for dry eye disease, such as artificial tear formulations, punctal plugs, and topical steroids, do not treat the underlying processes, and, thus, do not treat dry eye." *Id.* at 9-10.

On January 9, 2017, Allergan served a supplemental interrogatory response, elaborating on its bases for secondary considerations of nonobviousness. Ex. 4 at 7-11. In these responses, Allergan doubled-down on the statements made above and further asserted that a person of ordinary skill would not want to double the amount of castor oil because it reduced thermodynamic activity, reduced bioavailability of cyclosporin, and increased irritation. *Id.* at 7-9. Allergan repeated these assertions in its February 10, 2017 second supplemental response, and further asserted that "[b]ecause the 0.1% cyclosporin group contained twice the amount of drug, it would have been expected to achieve greater efficacy." Ex. 5 at 12, 2-17.

# B. References Cited in Dr. Calman's Report

On March 28, 2017, Defendants served the Opening Expert Report of Dr. Andrew F. Calman ("Report" or "Calman Report") (Doc. No. 341-1), which contained, among other things, Dr. Calman's opinions regarding the obviousness of the patents-in-suit, and further, that the asserted claims of the asserted patents were anticipated by Ding '979 and a publication by Sall describing the results of the Restasis® Phase 3 clinical trials. *See generally* Calman Report. Dr. Calman's Report proffered opinions grounded in the obviousness combinations and anticipatory art (1) disclosed in Defendants' invalidity contentions and (2) contained in Defendants' February 22, 2017 disclosure of reduced art. *Id.*; Doc. Nos. 340-1, 340-2, 340-3, 340-4. Notwithstanding

Allergan's assertions, Dr. Calman's Report provides no surprises nor does it violate the parties' agreement or the Local Patent Rules.

A description of each reference in dispute as it is used in Dr. Calman's Report is provided below. Each of these references either responds to Allergan's assertions of secondary considerations of nonobviousness, provides background relevant to the technology, or describes the state of the art. Notably, none of these references is cited as anticipatory or as part of an obviousness combination.

Reference in Dispute <sup>2</sup>	Allergan's Assertion	Dr. Calman's Reliance on Reference
Eadie	Not previously disclosed	<ul> <li>Rebuts Allergan's assertions of long-felt need, describing steroids as a treatment for keratoconjunctivitis sicca ("KCS") and/or dry eye</li> <li>Describes background relevant to technology</li> </ul>
		) Shows knowledge of skilled artisan at time of filing
Gaulhofer	Not previously disclosed	<ul> <li>Rebuts Allergan's assertions of long-felt need, describing steroids as a treatment for KCS and/or dry eye</li> <li>Describes background relevant to technology</li> <li>Shows knowledge of skilled artisan at time of filing</li> </ul>
Rolando	Not previously disclosed	<ul> <li>Rebuts Allergan's assertions of long-felt need, describing NSAIDs as a treatment for KCS and/or dry eye</li> <li>Describes background relevant to technology</li> <li>Shows knowledge of skilled artisan at time of filing</li> </ul>
Physician's Desk Reference	Not previously disclosed	<ul> <li>Describes background relevant to technology, using cyclosporin 2% in a topical solution for use in the eye</li> <li>Describes state of the art and knowledge of skilled artisan at time of filing</li> </ul>

<sup>&</sup>lt;sup>2</sup> Motion at 3 nn.2-3.

Reference in Dispute <sup>2</sup>	Allergan's Assertion	Dr. Calman's Reliance on Reference
Kanpolat	Not previously disclosed	<ul> <li>Rebuts Allergan's assertions of unexpected results, describing advantages of castor oil in treatment of KCS and/or dry eye</li> </ul>
		Describes background relevant to technology
		) Shows knowledge of skilled artisan at time of filing
Vieira	Not previously disclosed	Rebuts Allergan's assertions of unexpected results,     describing advantages of castor oil in treatment of KCS     and/or dry eye
		<ul> <li>Describes state of the art and knowledge of skilled artisan at time of filing</li> </ul>
Marsh & Pflugfelder	Previously Disclosed	J Rebuts Allergan's assertions of long-felt need, describing steroids as a treatment for KCS and/or dry eye
		Describes background relevant to technology
		J Shows knowledge of skilled artisan at time of filing
Stevenson	Previously Disclosed	<ul> <li>Describes state of the art and knowledge of skilled artisan at time of filing</li> </ul>
		Describes Restasis <sup>®</sup> clinical trials
Murphy	Previously Disclosed	Describes state of the art and knowledge of skilled artisan at time of filing
		J Describes Restasis <sup>®</sup> clinical trials
Turner	Previously Disclosed	Describes state of the art and knowledge of skilled artisan at time of filing
		) Describes Restasis® clinical trials

## II. ARGUMENT

# A. References Disclosed in Dr. Calman's Report Appropriately Rebut Allergan's Assertions of Secondary Considerations

Allergan's Motion wholly ignores that Defendants are entitled to rebut Allergan's contentions of secondary considerations of nonobviousness with references not explicitly elected as 35 U.S.C. §§ 102 or 103 art. Dr. Calman uses the Disputed References to counter Allergan's assertions of unexpected results and long-felt but unmet need, to provide background on the state

of the art, and show what a person of ordinary skill in the art ("POSA") would know at the time of the alleged invention. His disclosure is well within the bounds of the Local Patent Rules.<sup>3</sup>

Courts have consistently concluded that undisclosed or unelected references may be used to rebut, or are relevant to, allegations of secondary considerations of nonobviousness. *E.g.*, *Monarch Knitting Mach. Corp. v. Sulzer Morat GmbH*, 139 F.3d 877, 883-84 (Fed. Cir. 1998) (stating that disclosures that may not qualify as §§102 or 103(a) art and/or teach away may be relevant to the question of obviousness as a secondary consideration, *e.g.*, unexpected results, long-felt, but unmet need, and skepticism); *Medtronic Vascular Inc. v. Abbott Cardiovascular Sys., Inc.*, 614 F. Supp.2d 1006, 1028-29 (N.D. Cal. 2009) ("[E]ven if the references are not admissible as prior art, they are nonetheless admissible as evidence of both the ordinary level of skill in the art, and as a secondary consideration relating to obviousness."); *ThinkOptics, Inc. v. Nintendo of Am., Inc.*, No. 6:11-cv-455, 2013 WL 5934471, at \*1 n.1 (E.D. Tex. Sept. 11, 2013).<sup>4</sup>

The Kanpolat, Vieira, Turner, and Murphy articles cited by Dr. Calman provide basic background information explaining that castor oil was (1) a known anti-inflammatory agent; (2) used in cyclosporin ophthalmic emulsions to treat KCS long before the patents-in-suit were filed;

<sup>&</sup>lt;sup>3</sup> When Defendants served their initial invalidity contentions, Defendants did not know which, if any, secondary considerations Allergan would proffer. *See* P.R. 3-8(c)-(e) (requiring defendants to provide invalidity and non-infringement contentions before plaintiff serves infringement contentions).

<sup>&</sup>lt;sup>4</sup> Allergan contends that Defendants are attempting "an impermissible end-run around Defendants' agreement to narrow the number of prior art references." Motion at 4. Allergan is wrong. Defendants have respected the agreed-upon limits on prior art used to support claims of invalidity due to anticipation or obviousness; the Disputed References are not being cited or used for that purpose. Judge Davis, in *ThinkOptics*, similarly limited the number of asserted claims and prior art references with the express caveat that "this Order is not intended to limit the parties' use of other patents, publications, or instrumentalities for purposes other than as prior art, such as, *for example, the level of ordinary skill in the art, background of the technology at issue, or a motivation to combine references*." 2013 WL 5934471, at \*1 n.1 (emphasis added).

and (3) had therapeutic benefits for treating KCS and/or dry eye. *E.g.*, Calman Report ¶ 163, 164, 167. These references directly contradict Allergan's argument that an ophthalmic emulsion with "double the amount of castor oil" produced unexpected results because a POSA would not have increased the cylosporin A ("CsA") to castor oil ratio in an ophthalmic emulsion out of concern that it would reduce bioavailability to the ocular surface. Ex. 2 at 8-9. Allergan further asserted that it was somehow surprising that increasing the castor oil also increased the therapeutic efficacy of the formulation. *Id.* at 9. Yet, these four references directly contradict Allergan's assertions, and by doing so, provide context for Dr. Calman's opinions. In fact, the Murphy reference contains a quote from Dr. Steven Pflugfelder—an Allergan expert who submitted a report in this case—contradicting Allergan's argument: "The vehicle itself is better than any artificial tear." Calman Report ¶ 167; *see also* Ex. 8.

Dr. Calman similarly cites Stevenson to refute Allergan's allegations that a POSA would have expected castor oil to have no, or even negative, therapeutic effects for those suffering from KCS and/or dry eye. *E.g.*, Calman Report ¶¶ 166-167, 169, 698. Dr. Calman simply notes that Stevenson, which published several years before the patents-in-suit were filed, shows that there was nothing unexpected about the therapeutic efficacy of a 0.05% CsA emulsion; a POSA would have expected it to be just as therapeutically effective as a 0.01% CsA emulsion because Stevenson publicly disclosed in 2002 that there was no dose response relationship when comparing a 0.05% CsA and 0.4% CsA emulsion. *E.g.*, *id.* ¶¶ 232, 693-694, 697.

Allergan also argues that there was a long-felt, but unmet need for Restasis® because alternative treatments such as artificial tears, punctal plugs, and topical steroids, *e.g.*, corticosteroids, did not provide therapeutic relief for dry eye. Ex. 2 at 9-10. Dr. Calman cites Eadie, Gaulhofer, Rolando, and Marsh & Pflugfelder to rebut these assertions by providing basic information well-known to skilled artisans—that treatments like corticosteroids and non-steroidal anti-inflammatories ("NSAIDs") were used to decrease ocular inflammation long

before the alleged invention disclosed in the patents-in-suit. Calman Report ¶ 158; *see also id.* ¶¶ 700, 702.

While Dr. Calman and Defendants have used all the references in question in an appropriate manner, it bears noting that Defendants were initially only required to disclose the "legal theories and, in general, the factual bases of [their] claims or defenses." Doc. No. 77 at 2, Discovery Order. Defendants were not required to "marshal all evidence that may be offered at trial." *Id.* Thus, that some of the above references were not disclosed in Defendants' invalidity contentions does not mean that they are not relevant or admissible for purposes *other than* demonstrating invalidity due to anticipation or obviousness. Allergan does not—and cannot—deny that the Disputed References are directly relevant to secondary considerations and that Defendants are entitled to rely on them so long as they are not used as primary references in Defendants' anticipation or obviousness case.

# B. Dr. Calman's References Provide Background Information and Inform the State of the Art

Dr. Calman also uses each reference as background material to inform the state of the art. Allergan concedes, as it must, that Dr. Calman may do so. Motion at 5. Yet, Allergan wrongly alleges—without support—that Dr. Calman's citations to these references constitute "backdoor use" improperly showing motivations to combine elected prior art. *Id.* at 7. Allergan's allegations ring hollow and are contrary to law. *Ariosa Diagnostics*, 805 F.3d at 1365 (holding that references cited as "evidence of the background understanding of skilled artisans" need not be "pieces of prior art defining a combination for obviousness," explaining that such "[a]rt can legitimately serve to document the knowledge that skilled artisans would bring to bear in reading the prior art identified as producing obviousness") (citing *Randall Mfg.*, 733 F.3d at 1362–63).

L.P.R. 3-3 requires disclosure of each piece of prior art used to invalidate a patent under § 102 or § 103, but does not apply to references used as background material. iFLY Holdings LLC v. Indoor Skydiving Ger. GmbH, No. 2:14-cv-01080-JRG-RSP, 2016 WL 3680064, at \*2 (E.D. Tex. Mar. 24, 2016); Pozen Inc. v. Par Pharm., Inc., No. 6:08cv437-LED-JDL (Lead), 2010 WL 11431483, at \*8 (E.D. Tex. June 8, 2010). A party may use references not selected or disclosed under P.R. 3-3 to: (1) describe the state of the art; (2) provide background as to what a person of ordinary skill would have known at the time of the alleged invention; and (3) establish motivation to combine references. Ziilabs Inc. v. Samsung Elecs. Co., No. 2:14-cv-203-JRG-RSP, 2015 WL 7303352, at \*2 (E.D. Tex. Aug. 25, 2015); ThinkOptics, 2013 WL 5934471, at \*1 n.1 (holding that a limitation on the number of elected prior art references does not "limit the parties' use of other patents, publications, or instrumentalities for purposes other than as prior art, such as, for example, . . . a motivation to combine references"); Better Mouse Co. LLC v. SteelSeries ApS, No. 2:14-cv-198-RSP, 2016 WL 3611560 at \*1 (E.D. Tex. Jan. 5, 2016) (allowing use of unelected references to discuss state of the art). Here, the few references Dr. Calman cites that were not contained in Defendants' invalidity contentions are properly cited and used as background material in accordance with the law and the Local Patent Rules.

The Eadie, Gaulhofer, Rolando, Physician's Desk Reference ("PDR"), and Marsh & Pflugfelder references ("Other Treatment" references) are cited only in paragraphs within the "Technology Tutorial" section of Dr. Calman's report,<sup>5</sup> which specifically discusses what treatments for dry eye and/or KCS were "known and available as of [the priority date of the asserted patents]," including topical corticosteroids, NSAIDs, and a 2% CsA topical solution

<sup>&</sup>lt;sup>5</sup> With the exception of ¶¶ 163 and 166-67, none of the passages from Dr. Calman's Report that Allergan cites in its Motion reference any of the art Allergan seeks to strike. Motion at 6.

Calman Report ¶ 158-159, 162. In other words, these particular references are used only to describe the state of the art and provide background information as to what a POSA would know at the time of the alleged invention. These references are not used for any other purpose in the Calman Report, nor are they relied on in the specific grounds for anticipation and obviousness underlying Dr. Calman's invalidity opinion. Allergan never explicitly argues that the Other Treatment references are used in any manner exceeding the scope of allowable background use.

Instead, Allergan's argument focuses solely on the Kanpolat, Vieira, Stevenson, Murphy, and Turner references, which Allergan alleges are "mask[ed] . . . as background" material but used as invalidating § 103 prior art. *See* Motion at 5-7. Even a cursory review of Dr. Calman's report reveals that Allergan is wrong.

Dr. Calman cites to Kanpolat, Vieira, Murphy, and Turner only in the "Technology Tutorial" section of his Report. These paragraphs discuss: (1) the relevant properties of castor oil (Kanpolat, Vieira); and (2) the historical, public record of the Allergan Restasis® clinical trials showing the benefits of the tested castor oil vehicle (Murphy, Turner). Calman Report ¶¶ 163, 166-167. Again, these references are used only to describe the state of the art and provide background information as to what a person of skill would know about the use of castor oil in ophthalmic emulsions at the time of the alleged invention. Kanpolat, Vieira, Murphy and Turner are not a part of the anticipation or obviousness combinations on which Defendants rely to contend the asserted patents are invalid.

Similarly, the Stevenson reference is cited simply to establish the historical, public record of Allergan's overall findings during the Phase 2 Restasis<sup>®</sup> clinical trials. Indeed, Allergan's own expert, Dr. Perry, faulted Dr. Calman for not "rely[ing] on [Stevenson] in [his] prior art analysis." Ex. 6, ¶ 95; *see*, *e.g.*, Calman Report ¶¶ 167, 169, 232, 241, 315, 327, 351, 693-94,

697-98, 709. Accordingly, Dr. Calman's use of the Kanpolat, Vieira, Murphy, Turner, and Stevenson references falls squarely within the bounds of acceptable use to describe the background of the technology and therefore show the knowledge of a POSA at the time of invention. *Genentech, Inc. v. Trustees of Univ. of Pa*, No. C 10–2037 LHK (PSG), 2012 WL 424985, at \*3 (N.D. Cal. Feb. 9, 2012) (holding that an expert's citation to twenty undisclosed references discussing the "known history" of relevant clinical trials did not "go beyond" the scope of the Local Rules); *iFly Holdings*, 2016 WL 3680064, at \*2 (denying motion to exclude references that were used solely to explain the relevant technology and were not used to "contend [that] any of the [references] anticipat[ed] or ma[de] obvious the Asserted Patent").

Even if Allergan were correct that Dr. Calman relies on these references to show that a POSA would have been motivated to increase the amount of castor oil disclosed in a prior art formulation to arrive at the claimed formulation, such use would be proper. See Motion at 6; *ThinkOptics*, 2013 WL 5934471, at \*1 n.1. Moreover, Dr. Calman does not rely upon these references in obviousness combinations or assert them as anticipatory. Rather, they provide background information, inform the state of the art, and rebut Allergan's assertions of secondary considerations of nonobviousness; thus, Dr. Calman's use of these references complies with the Local Patent Rules. *Finjan, Inc. v. Sophos, Inc.*, No. 14-cv-01197-WHO, 2016 WL 2988834, at

<sup>&</sup>lt;sup>6</sup> Because the Local Patent Rules in this District were modeled after the rules adopted by the Northern District of California, opinions from N.D. Cal. regarding its own local patent rules are considered persuasive. *Finisar Corp. v. DirecTV Group, Inc.*, 424 F.Supp.2d 896, 897, n.1 (E.D. Tex. 2006).

<sup>&</sup>lt;sup>7</sup> The knowledge of a skilled artisan necessarily informs their motivation.

<sup>&</sup>lt;sup>8</sup> The caselaw Allergan cites to support its assertions is unpersuasive. Motion at 6-7 (citing *Ziilabs Inc.*, 2015 WL 7303352, at \*2 (allowing reliance on undisclosed background references); *Life Techs. Corp. v. Biosearch Techs., Inc.*, No. C 12-00852 WHA, 2012 WL 4097740, at \*2 (N.D. Cal. Sept. 17, 2012) (excluding citation to unelected background references but later noted to be out of synch with the majority of caselaw in N.D. Cal. allowing use of such references); (continued...)

\*12 (N.D. Cal. May 24, 2016) (holding use of undisclosed background references is not improper or considered § 103 art so long as they are not used to show that particular claim limitations were present in the prior art, *i.e.*, relied on in obviousness combination); *see also Pozen*, 2010 WL 11431483, at \*8 (holding use of background art permissible so long as those references are not "relied upon for the express purpose of invalidating the patents-in-suit").

## C. There is No Prejudice to Allergan

Allergan has suffered no undue prejudice or surprise here. Allergan concedes that

Defendants disclosed four of the Disputed References in their invalidity contentions. Motion at

3; see also O2 Micro Int'l, Ltd. v. Monolithic Power Sys., Inc., 467 F.3d 1355, 1365-66 (Fed. Cir.

2006) (stating purpose of Local Rules are to provide notice to all parties of issues in litigation);

accord Realtime Data, LLC v. Packeteer, Inc., No. 6:08-cv-144, 2009 U.S. Dist. LEXIS 122434,

at \*8 n.3 (E.D. Tex. July, 20, 2009) (same). The other six references should be of no surprise to

Allergan because they address issues of secondary considerations Allergan affirmatively set forth

in its original interrogatory responses. Indeed, Allergan's claim construction expert, Dr.

Noecker, addressed alternative treatments for KCS and dry eye—relevant to long-felt need—

<sup>(...</sup>continued from previous page)

*Pactiv Corp. v. Multisorb Techs., Inc.*, No. 10 C 461, 2013 WL2384249, at \*2 (N.D. Ill. May 29, 2013) (out-of-district case contrary to the well-established law in this District allowing use of unelected background references); *Emcore Corp. v. Optium Corp.*, CIV. A. No.7–326, 2009 WL 3381800, at \*2 (W.D. Pa. Oct. 16, 2009) (same)).

Allergan also relies on *Metaswitch Networks Ltd. v. Genband US LLC*, No. 2:14-cv-744-JRG-RSP, 2016 WL 3618831, at \*6 (E.D. Tex. Mar. 1, 2016), which grants, without discussion, a motion *in limine* to exclude art in the background section of an expert report describing the technology. Motion at 4. However, Judge Payne, the presiding judge in *Metaswitch*, has repeatedly held, on facts similar to the present case, that a party may use unelected references to discuss background information and/or the state of the art. *See iFly Holdings*, 2016 WL 3680064, at \*2; *Better Mouse*, 2016 WL 3611560, at \*1; *Ziilabs*, 2015 WL 7303352, at \*2.

during his deposition in July 2016. *E.g.*, Ex. 7 at 41:13-42:8 (discussing corticosteroids as treatment for dry eye and/or KCS).

This is not an instance where new obviousness combinations were disclosed at the last minute. *E.g.*, *LML Patent Corp.v. JPMorgan Chase & Co.*, No. 2:08-cv-448, 2011 WL 5158285, at \*7 (E.D. Tex. Aug. 11, 2011) (striking Defendants' addition of *twenty-eight new obviousness combinations*); *Tyco Healthcare Group LP v. Applied Med. Res. Corp.*, No. 9:06-cv-151, 2009 WL 5842062, at \*3 (E.D. Tex. Mar. 30, 2009) (striking expert testimony regarding Defendants' last-minute disclosure of new obviousness combinations). Nor do Defendants use the Disputed References as grounds for their primary invalidity case. Further, Allergan's experts have had a full opportunity to address the Disputed References and Allergan's counsel have had the opportunity to cross examine Dr. Calman about them. Allergan does not identify any legally cognizable prejudice—nor can it—resulting from Dr. Calman's reliance on the Disputed References.

# III. CONCLUSION

For the foregoing reasons, Defendants request that the Court deny Allergan's motion to strike the Disputed References from Dr. Calman's Report and deny Allergan's request to restrict Dr. Calman's trial testimony from discussing the same.

Dated: June 13, 2017

## /s/ J.C. Rozendaal

J.C. Rozendaal (pro hac vice)
Michael E. Joffre (pro hac vice)
Pauline M. Pelletier (pro hac vice)
R. Wilson Powers III (pro hac vice)
STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.
1100 New York Ave. NW, Suite 600

Washington, DC 20005 Tel: 202-371-2600 Fax: 202-371-2540 jcrozendaal@skgf.com mjoffre@skgf.com ppelletier@skgf.com tpowers@skgf.com

Louis B. ("Brady") Paddock Texas Bar No. 00791394 NIX, PATTERSON & ROACH L.L.P. 2900 St. Michael Drive, Ste. 500 Texarkana, TX 75503 (903) 223-3999 (903) 223-8520 (fax) bpaddock@nixlawfirm.com

# COUNSEL FOR DEFENDANT TEVA PHARMACEUTICALS USA, INC.

#### Respectfully submitted,

#### /s/ Anna G. Phillips

Douglas H. Carsten Wendy Devine Christina E. Dashe Alina L. Litoshyk Nellie J. Amjadi

WILSON SONSINI GOODRICH & ROSATI 12235 El Camino Real, Suite 200 San Diego, CA 92130-3002

Tel: 858-350-2300 Fax: 858-350-2399 dcarsten@wsgr.com wdevine@wsgr.com cdashe@wsgr.com alitoshyk@wsgr.com namjadi@wsgr.com

Anna G. Phillips

Texas Bar No. 24090329
WILSON SONSINI GOODRICH & ROSATI
900 South Capital of Texas Highway
Las Cimas IV, Eifth Floor

Las Cimas IV, Fifth Floor Austin, TX 78746-5546 Tel: 512-338-5400

Fax: 512-338-5499 anphillips@wsgr.com

Melissa Smith

Allen Franklin Gardner GILLAM & SMITH LLP 303 S. Washington Ave. Marshall, Texas 75670

Tel: 903-934-8450 Fax: 903-934-9257

melissa@gillamsmithlaw.com allen@gillamsmithlaw.com

COUNSEL FOR DEFENDANTS MYLAN PHARMACEUTICALS INC. AND MYLAN INC.

#### /s/ Michael R. Dzwonczyk

Michael R. Dzwonczyk Azadeh Kokabi Mark Boland SUGHRUE MION PLLC 2100 Pennsylvania Ave NW, Suite 800

Washington, DC 20037
Tel: 202-293-7060
Fax: 202-293-7860
mdzwonczyk@sughrue.com
akokabi@sughrue.com
mboland@sughrue.com

Earl Glenn Thames, Jr.
POTTER MINTON
110 N College Avenue, Suite 500
Tyler, TX 75702
Tel: 903-597-8311
Fax: 903-593-0846

COUNSEL FOR DEFENDANT AKORN, INC.

glennthames@potterminton.com

#### /s/ Stephen R. Smerek

Stephen R. Smerek (pro hac vice)
Shilpa Coorg (pro hac vice)
Jason Craig Hamilton (pro hac vice)
WINSTON & STRAWN LLP
333 South Grand Avenue, 38th Floor
Los Angeles, CA 90071-1543
Tel: 213-615-1933

Fax: 213-615-1933 Fax: 213-615-1750 ssmerek@winston.com scoorg@winston.com jhamilton@winston.com

Charles B. Klein (pro hac vice) WINSTON & STRAWN LLP 1700 K Street, NW Washington, DC 20006 Tel: 202-282-5977 Fax: 202-282-5100 cklein@winston.com

Deron R. Dacus
Peter Aaron Kerr
THE DACUS FIRM, PC
821 ESE Loop 323, Suite 430
Tyler, TX 75701
Tel: 903-705-1117
Fax: 903-581-2543
ddacus@dacusfirm.com
pkerr@dacusfirm.com

COUNSEL FOR DEFENDANT INNOPHARMA, INC.

#### /s/ Peter Curtin

William A. Rakoczy

Peter Curtin

Paul J. Molino

John D. Polivick

Kevin P. Burke

Patrick N. Abbott

RAKOCZY MOLINO MAZZOCHI SIWIK LLP

6 West Hubbard Street, Suite 500

Chicago, Illinois 60654

Tel: (312) 222-6301

Fax: (312) 222-6321

wrakozcy@rmmslegal.com

pcurtin@rmmslegal.com

paul@rmmslegal.com

jpolivick@rmmslegal.com

kburke@rmmslegal.com

pabbott@rmmslegal.com

Eric H. Findlay

Texas Bar No. 00789886

Walter Wayne Lackey, Jr.

Texas Bar No. 24050901

FINDLAY CRAFT, P.C.

102 North College Avenue, Suite900

Tyler, TX 75702

Tel: (903) 534-1100

Fax: (903) 534-1137

# COUNSEL FOR DEFENDANT FAMY CARE LIMITED

# **CERTIFICATE OF SERVICE**

The undersigned hereby certifies that a true and correct copy of the above and foregoing document has been served on August 24, 2017 to all counsel of record who are deemed to have consented to electronic service via the Court's CM/ECF system per Local Rule CV-5(a)(3).

/s/ Melissa R. Smith
Melissa Smith